

AGENDA

CIRCULATORY SYSTEM DEVICES PANEL

March 5, 2001

Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Boulevard, Gaithersburg, MD

8:00 – 3:00pm	PMA Discussion, Recommendations, and Voting	
8:00 a.m.	Call to Order	Warren Laskey, M.D., Acting Chairperson
8:05 – 8:15 a.m.*	Open Public Hearing*	
8:15 – 9:15 a.m.	Sponsor Presentation: Medtronic Corporation P010031, Medtronic® InSync ICD® System Model 7272 William T. Abraham M.D., University of Kentucky James B. Young, M.D., Cleveland Clinic Foundation Angel R. Leon, M.D., Emory University	
9:15 – 10:15 a.m.	FDA Presentation Doris Terry, lead reviewer Helen S. Barold, M.D., clinical reviewer Gerry Gray, Ph.D., statistical reviewer	
10:15 – 10:30 a.m.	Break	
10:30 a.m. – 12:00 p.m.	Open Committee Discussion	Warren Laskey, M.D.
12:00 p.m.	Adjourn – Break for Lunch	
1:00 p.m.	Call to Order , Open Committee Discussion, Recommendations and Voting	Warren Laskey, M.D.
2:45 – 3:00 p.m.*	Open Public Hearing*	
3:00 p.m.	Adjourn	

OPEN PUBLIC HEARINGS*

Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee.

Dr. Ewing will present the speakers who have requested time for presentation to the Panel. After the scheduled speakers have spoken, the Chair may ask them to remain if the committee wishes to question them further. Dr. Laskey will recognize unscheduled speakers as time allows.

Note: Only the Chair and members of the Panel may question speakers during the open public hearing.